

Comparison of Topical Lidocaine [2%gel] and Injectable Lidocaine [2% solution] for Incision and Curettage of Chalazion in Ilorin, Nigeria

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Summary

Aims and objectives: To compare the efficacy and side effects profile of topical 2% lidocaine gel with injectable 2% lidocaine solution as local anaesthetics for incision and curettage of chalazion.

Patients and Methods: Over a 12 month period, 61 patients with unilateral chalazia who were scheduled for incision and curettage surgery under local anaesthesia were randomized into 2 groups: A & B. Group A received 1.5ml of injectable lidocaine as local anaesthetic while Group B received 1.5ml of lidocaine 2% gel topically. The major outcome of interest was pain experienced during anaesthetic administration and surgery.

Results: Mean pain score from anaesthesia administration was significantly higher in the injection group ($A = 4.46$ vs. $B = 0.57$), ($p = 0.000005$). There was a statistically significant difference in mean pain score during incision and curettage with more pain in the gel group ($A = 2.84$ vs. $B = 4.83$), ($p = 0.0012$). However, the mean total pain score (surgery plus anaesthesia) was more in the injection than the gel group ($A = 7.3$ vs. $B = 5.4$) ($p = 0.0094$). The proportions that had no fear for injection were 54.8 % in A and 56.7 % in B. Group A had significantly more ptosis than Group B (2.2 vs 1.4 , $p = 0.00003$). Bleeding occurred in 93.5% in group A while none occurred in Group B ($p = 0.000$).

Conclusion: Lidocaine 2% gel is an effective, safe and convenient alternative to injectable lidocaine 2% as local anaesthetic agent in incision and curettage for Chalazion in this study.

Key words: chalazion, incision and curettage, local anaesthesia, lidocaine, pain assessment

Introduction

Minor ocular surgeries are procedures, which can be performed on outpatient basis without encountering any serious risk to vision or life of the patients¹. These surgeries are usually done under local anesthesia on an outpatient basis. Hospital records revealed that minor ocular surgeries constitute about fifteen per cent of all surgical procedures at the Department of Ophthalmology of the University Teaching Hospital, Ilorin, Nigeria [UTH]. Ilorin is located in the savannah North Central Zone of Nigeria [longitude 4.32E and latitude 8.30N].

Chalazion is a nodular, usually painless tumefaction of the eye lid. It is a chronic granulomatous inflammation of the Meibomian gland and the gland of Zeis, apparently caused by stasis of the sebaceous secretion from these

glands. It is more common in the upper eye lid than the lower eyelid because there are more sebaceous glands in the tarsal plate of the upper eyelid. It occurs in all age groups but commonly in the 20-40 year age bracket¹⁻⁵. It affects all races. People with chronic seborrheic blepharitis and acne rosacea are at higher risk of developing the disorder². More often than not, the patient comes to the physician because of the cosmetic blemish. A large chalazion can cause undue pressure on the globe on blinking, and may press on the cornea and induce blurred vision from astigmatism and the attendant symptoms of asthenopia. Complete spontaneous regression is rare. Delayed treatment of a chalazion may lead to perforation toward the conjunctival sac resulting in an enlarging polypoid mass (granuloma pyogenicum)^{1,2}. The use of intra-lesional steroid has been suggested for small multiple

lesions, however, incision and curettage is more effective in larger lesions and a combination of the above surgical and medical methods could be more effective than either of the two used alone⁶⁻⁹.

Incision and curettage is usually done under local anaesthesia cover, which is commonly administered by transcutaneous infiltration of skin and subcutaneous tissues. An injection of a local anaesthetic is usually painful and constitutes an unpleasant experience for a patient¹⁰⁻¹⁵. If a struggling child or an uncooperative patient is involved, there is risk of injury to the globe from the injection needle. Other possible complications include bleeding from the injection site, haematoma collection and ocular damage if the injection needle accidentally penetrates the globe. The paediatric age group is at greater risk of the above complications because they are unlikely to cooperate fully with the procedure¹¹. General anaesthesia, which is a possible alternative, involves rendering the patient unconscious with the assistance of an anaesthetist and relevant technology. It is therefore more costly and carries a higher risk of anaesthetic morbidity and mortality than local anaesthesia¹⁶.

Lidocaine 2% gel applied topically has already been found to be effective in cataract¹⁷ and strabismus surgery¹⁸. Studies have demonstrated the effectiveness of lidocaine gel in controlling pain in incision and curettage of chalazion as well as pterygium excision^{11,19}. The potential roles of this local anesthetic agent among patients having chalazion surgery have not yet been established among Nigerians. Documented literatures on previous studies in this area are scanty and appear to be non-existent in Nigeria, to the best of our knowledge.

This study therefore aims at comparing the use of topical lidocaine gel with the infiltrative 2% lidocaine in an African setting.

Subjects, materials and methods

The study involved all patients aged fifteen years and above with chalazion, who had been scheduled for incision and curettage at the Department of Ophthalmology University of Ilorin Teaching Hospital Ilorin (UIITH) and Civil Service Hospital, Ilorin. The study lasted for a period of 12 months from January to December 2006.

Ilorin is the capital city of Kwara state in the Guinea Savannah belt of North Central Zone of Nigeria. The Ophthalmology Department of UIITH is a referral center for hospitals in Kwara State and the surrounding states of Kogi, Oyo, Osun, Niger, Kebbi and Sokoto.

Selection of subjects: All consecutive patients with chalazion that had been adjudged to need incision and curettage by their attending ophthalmologist were pooled after randomization to either topical anaesthesia or the injectable anaesthesia. Patients were randomized systematically as they presented in the department for surgery, and were alternately assigned into group A (injectable anaesthesia) and group B (topical anaesthesia). The other inclusion criteria were patients being 15 years and above in age, undergoing incision and curettage for chalazion for the first time, and being a Nigerian of black race living within the study locality and environs.

The exclusion criteria included patients less than 15 years of age, having had previous lid surgery, and those with scars on the eyelid. Other exclusion criteria were

patients with previous systemic condition requiring regular use of analgesic, patients with suspicious tumefactions, and psychologically disturbed patients, and those with previous hypersensitivity to lidocaine.

Consent: Institutional consent was obtained from the University of Ilorin Teaching Hospital's Ethical and Research committee. Informed consent was also obtained from individual patient who participated in the study.

Sample size determination: Based on a prevalence rate of chalazion of 3.4% (deduced from a review of our hospital records), precision of 0.05, and a 95% confidence limit, a minimum sample size of 53 patients was required.

Administration of anaesthesia: In order to reduce any bias that could have arisen from recruitment and subsequent treatment, anaesthesia option was only revealed to the surgeon after randomisation of a patient to a study group. One of the authors (OOO) performed the administration of anaesthesia, surgery, assessment of pain, and measurements of lid swelling. The Patient was put in the supine position on the couch in the minor procedure room of the department, 0.5% Tetracaine drops were applied into both the upper and lower conjunctival cul-de-sacs. Routine cleaning of affected lid and conjunctival sac was done using 5% povidone iodine solution and draping exposing the affected lid was applied. 1.5ml. of gel lidocaine 2% without adrenaline measured using 2ml. hypodermic syringe was used in group B. The 1.5ml. topical gel was applied into the conjunctiva sac and over the affected eye lid while the patient was in the supine position and five minutes was given for the drug to take effect. Injectable anaesthesia was applied in group A using 1.5ml. of lidocaine in a 2ml. disposable hypodermic syringe. This was injected subcutaneously around the lesion. The same time of five minutes was given after local injection with equal volume of the injectable solution. Patient's pain from the administration of anaesthesia was assessed immediately using the Verbal Numerical Scale pain assessment tool. The absence or presence of bleeding from the site of administration on the lid immediately post anaesthesia was noted. Lid oedema post anaesthesia as evidenced by pseudo-ptosis was assessed immediately from the difference in margin reflex distance of the lid before and after administration of anaesthesia. The margin reflex distances; (MRD 1) for upper lid, (MRD 2) for lower lid were measured using a transparent metre rule.

Surgery: The incision and curettage surgery involved placing a chalazion clamp over the entire lesion to secure haemostasis, a vertical incision to the lid margin was then made over the lesion on the tarsal conjunctiva, the contents were then drained and the sac curetted. Antibiotic ointment was applied and the eye was pressure patched for ten minutes to secure haemostasis. Pain assessment was done immediately after surgery using the verbal numerical scale. Post surgery lid oedema was assessed from the difference in pre anaesthetic marginal reflex distance and post surgery margin reflex distance in millimeters. The bleeding, which in this study means bleeding overflowing the conjunctiva sac was noted after ten minutes of pressure patching. Patient responded to other research concern in the data form immediately after surgery (10 minutes).

Assessment of pain: Pain assessment was done at two stages of the procedure; immediately post anaesthesia and immediately post surgery. The pain score, which had

been explained to the patient pre-operatively to ensure understanding, was done in all the patients using the simple, verbal numerical scoring scale of 0 to 10. (0- no pain, 10- worst pain ever). Total mean pain was taken as the sum of mean pain for anaesthesia and mean pain for surgery.

Assessment of fear of injection: Fear of injection was assessed using the verbal numerical scoring scale of 0 to 10 (0 =no fear 10 = worst fear ever)

Assessment of lid swelling/pseudoptosis: Eyelid oedema arising from anaesthetic fluid injection into the eye lid, transient paresis of the levator muscle, and intra tissue haemorrhage are known complications that commonly present as pseudoptosis after administration of anaesthesia and surgery.

All enrolled subjects had their lid position assessed before anaesthesia, after anaesthesia, and after surgery. The margin reflex distance (MRD) was used and was measured in primary position of gaze.

Subjects' perception of unpleasant steps: The subjects were asked to subjectively indicate which aspect of the procedure: clamp application, administration of anaesthesia or surgery, was the most unpleasant

Level of education: Educational status was compared between the two groups at four levels of no formal education; Arabic and Western, primary for subjects who had both Arabic and Western primary education, secondary (Arabic and Western post primary) tertiary (Arabic and Western post secondary education).

Data analysis: The data generated from the research was analyzed using EPI - info 6, EPI- info 2002 and excel computer software programme. Frequency tables were generated. Means were compared using F statistics while proportion were compared using the chi square (χ^2) test of significance. The level of statistical significance was set at $p < 0.05$.

Results

Sixty-one eyes (61) from sixty-one (61) patients were operated on and analyzed in this study. All subjects were black Africans from Ilorin and environs. Thirty-one of these eyes were randomized into group A (injectable anaesthesia) and the remaining 30 into group B (topical anaesthesia). No patient refused his/her own allocated group. None of the study subjects was unable to tolerate incision and curettage as a result of inadequate anaesthesia. All patients received the designated mode of anaesthesia. No patient in the gel group required conversion to conventional injectable anaesthesia because of inadequate anaesthesia by lidocaine gel 2%. Table i illustrates a comparative breakdown of the various socio-demographic characteristics.

Age and sex distribution: The population distribution of the age ranges in the two groups which were comparable are as detailed in Table I. There was no statistically significant difference in sex proportion, $p = 0.72$ (Yates corrected, $\chi^2 = 0.13$) between the two study groups. **Education:** Majority of the subjects attained literacy level above primary education, 90.4 % in A, 86.7% in B, though 6.5% of subjects in group A had no formal education whatsoever. Though group B appears to be more educated, there was no statistically significant difference in the levels of education in both groups p -value = 0.27, (Yates corrected

$\chi^2 = 0.22$).

Fear of injection: A near-equal proportion of the study population had no fear for injection: 54.8 % in A and 56.7 % B. The highest fear score of 8 was recorded in 2 (6.5%) of group A and 2 (6.7%) of group B. The mean score was low and same for both groups: 2.0 (table ii).

Pain scores: The pain score results in Group A for pain borne during anaesthesia showed a score of 2 and below in 29.1% of the study population while 100% of group B subjects had pain scores of 2 and below. The ranges of pain scores were a minimum pain score of 1 in 2 patients (6.5%) and maximum pain score of 8 in 2 patients (6.5%) in group A while group B had a minimum pain score of 0 in 18 patients (60%) and maximum score of 2 in 5 patients (16.7%), the remaining 7 patients (23.3%) had a score of 1. The mean pain scores were 4.4 (SD-2.0) in Group A and 0.6 (SD 0.8) for group B (table iii). There was a statistically significant difference $P = 0.000005$, (F statistic value = 91.89).

Pain score for surgery in Group A ranged from a minimum of 0 in 6 (19.4%) patients to a maximum of 8 in 1 (3.2%) patient, and a minimum score of 2 in 8 (26.7%) patients to a maximum of 8 in 5 (16.7%) subjects in group B. In the injectable group A, 26 patients (83.9%) of the population had pain score of 5 and less (Table IV), while 16 subjects (53.3%) had pain score of 5 and less in the gel group (Table IV). The mean score of pain due to surgery was 2.8 (SD 2.4) in group A and 4.8 (SD 2.2) in group B (table iv). There was a statistically significant difference between these mean pain scores for surgery with $p = 0.001190$, (F statistic 11.53).

The total mean pain score which is the mean of the sum of pain of anaesthesia and surgery in Group A was 7.3 (SD 3.0) and Group B was 5.4 (SD 2.4). There was a statistically significant difference $p = 0.009441$.

The mean difference in margin reflex distance (MRD) in Group A after anaesthesia was 1.5 (SD .0.6) and Group B had no change in MRD post anaesthesia. The total ptosis which was measured as the difference between presentation and post surgery MRD gave a mean difference after surgery in Group A of 2.2 (SD 0.63) and Group B of 1.4 (SD 0.49), $p = 0.00003$, (F Stat- 26.33). (table v).

Bleeding during injectable anaesthesia was a significant problem in group A, 93.5% bled from anaesthesia while no subject in group B bled from gel anaesthesia. There was a significant difference between the proportion of bleeders in these two groups with p -value = 0.00. After ten minutes of pressure patching post surgery, 93.5% of group A stopped bleeding and 100% group B secured haemostasis too. There was no statistically significant difference p -value = 1.0.

The unpleasant steps of the procedure were divided into pressure from chalazion clamp administration and pain from anaesthesia administration and surgery. The pressure effect from the application of chalazion clamp was the unpleasant step in 8 patients (26%) in Group A and in 16 (53%) in Group B. Group B had more unpleasant experience from application of clamp $p = 0.005$. Anaesthesia administration was not unpleasant in Group B respondents, whereas 20 (64.5%) of Group A found it unpleasant, p -value = 0.0004. A significant proportion of Group B 14 (46.7%) indicated surgery as their most unpleasant step while only 3(9.7%) of Group A did, p -

value = 0.0033. Overall, clamp pressure accounted for 39.5%, pain from injectable anaesthesia 32.5% and pain from surgery 28.2% of the unpleasant responses in the 61 subjects that participated in the study.

Table i:
Comparative analysis of the socio-demographic characteristics of subjects who had injectable (Group A) with those that had topical (gel) lidocaine (Group B).

Variables	Group A n ₁ =31(%)	Group B n ₂ = 30(%)	X ² /F stat	P. value
Age:				
Range	15-68	17-55	0.00(F)	0.965103
Mean	29.7	29.8		
S.D	11.1	10.6		
Gender				
:Male	8 (18)	10 (33.3)	0.13(x ²)	0.72
Female	23 (74.2)	20 (66.7)		
Educational status				
Nil	2 (6.5)	0 (0)	3.88(x ²)	0.27
Primary	1 (3.2)	4 (13.3)		
Secondary	6 (19.4)	6 (20.0)		
Tertiary	22 (71)	20 (66.6)		

SD: Standard Deviation

n1: Observable Numbers in Group 1

F-Stat: F-Statistics

n2: Observable Numbers in Group B

X²: Chi-Square

P V= P-Value

Table ii:
Fear scores among subjects who had injectable (Group A) with those that had topical (gel) lidocaine (Group B).

Findings	Group An=31(%)	Group Bn=30(%)	X ² /F statistics	P. Value
Fear score				
0	17 (54.8)	17 (56.7)		
1	0 (0)	1 (3.3)		
2	2 (6.5)	2 (6.7)		
3	4 (12.9)	1 (3.3%)		
4	2 (6.5)	3 (10.0)		
5	3 (9.7)	2 (6.7)		
6	0 (0)	0 (0)		
7	1 (3.2)	2 (6.7)		
8	2 (6.5)	2 (6.7)		
Range	0-8	0-8		
Mean	2.0	2.0		
SD	2.6	2.8		

Table iii:
Comparison of mean pain scores during Anaesthesia in subjects who had injectable (Group A) with those that had topical (gel) lidocaine (Group B).

Findings	Group An=31(%)	Group Bn=30 (%)	X ² /F statistics	P. Value
Pain score				
0	0 (0)	18 (60.0)		
1	2 (6.5)	7 (23.3)		
2	7 (22.6)	5(16.7)		
3	0 (0)	0 (0)		
4	6 (19.4)	0 (0)		
5	9 (29.0)	0 (0)		
6	1 (3.2)	0 (0)		
7	4 (12.9)	0 (0)		
8	2 (6.5)	0 (0)		
Range	1-8	0-8		
Mean	4.4	0.5		
SD	62.03	70.77	91.9	0.000005

Table iv:
Comparison of mean pain score during Surgery in subjects
who had injectable (Group A) with those that had topical (gel) lidocaine (Group B).

Findings	Group An=31(%)	Group Bn=30(%)	X ² /F statistics	P. Value
Pain score				
0	6 (19.4)	0 (0)		
1	5 (16.1)	0 (0)		
2	6 (19.4)	8 (26.7)		
3	4 (12.9)	1 (3.3)		
4	0 (0)	4 (13.3)		
5	5 (16.1)	3 (10.0)		
6	2 (6.5)	8 (26.7)		
7	2 (6.5)	1 (3.3)		
8	1 (3.2)	5 (16.7)		
Range	0-8	2-8		
Mean	2.8	4.8		
SD	42.41	32.17	11.53	0.001190

Table v:
Comparison of lid swelling/pseudoptosis post anaesthesia
in the injectable (Group) with those that had topical (gel) lidocaine (Group).

Findings	Group An = 31(%)	Group Bn = 30 (%)	X ² /F statistics	P. Value
Diff. In MRD (mm)				
0	0 (0)	1 (3.3)		
1	4 (12.9)	10 (33.3)		
1.5	1 (3.2)	10 (33.3)		
2	12 (38.7)	9 (30.0)		
2.5	7 (22.6)	0 (0)		
3	7 (22.6)	0 (0)		
Range	1-3(mm)	0-2 (mm)		
Mean	2.2	1.4		
SD	0.63	0.49	26.33	0.000003

Discussion

Lidocaine 2% gel had been found useful in cataract surgery¹⁴, strabismus surgery¹⁵ and pterygium excision¹⁶, but studies on its efficacy in incision and curettage for chalazion are scanty¹¹. The fear of injection among the study groups was low and almost equal in both groups. This finding is different from what Li RTH and co workers found in Kwun Tong, Hong Kong [People Republic of China]¹¹. The low scores and similarities in the two groups further eliminate the possibilities of bias. Any bias due to surgeon variation had also been eliminated as all the measurements and surgery were done by a single surgeon (OO).

Overall patient in group A experienced more pain, the mean of total pain experienced by study subject in group A 7.3 [SD 3.0] was in excess of that of group B 5.4 [SD 2.4] and this was statistically significant at $P = 0.009$. The pain from anaesthesia accounted for the difference in these two groups. Even though the patients in group B had more pain from the surgical procedure, with mean pain score 4.8 [SD 2.2], as against a mean score of 2.8 [SD 2.4] in group A, with P value of 0.001, this difference was eroded by pain experienced during anaesthesia, which was more

in the injection group ($A = 4.4$ vs. $B = 0.6$, $p = 0.000005$). This finding is in agreement with previous study done in Hong Kong and Turkey^{11,19}.

The Verbal Numerical Scale that was used in this study has been demonstrated to be comparable to the Visual Analogue Scale that was used in earlier similar studies²⁰⁻²². Hence our findings using the Verbal Numerical Scale should be valid.

Systemic complication was not experienced by any of the subjects. The local complications of lid oedema, and lid ptosis were assessed by the difference in margin reflex distance. There was a noticeable significant difference in Margin Reflex Distance (MRD) value in group A which was not observed in group B, post anaesthesia. Post surgery, this difference was maintained in margin reflex distance between the two groups. These findings are not unexpectedly out of place as infiltrative anaesthesia is more likely to provoke intra tissue haematoma which stretches and weakens the levator aponeurosis. Difference in the severity of ptosis could become relevant in a patient with an only eye having surgery on the lid of the good eye, cases of bilateral lid surgery or patient who for cosmetic reason may not want to pad the eye post surgery.

Bleeding post anaesthesia was not seen in group B

as was the case with nearly all (93.5%) the study subjects in group A. The risk of blood borne communicable diseases is reduced in this stage of the procedure considering the invasive nature and the use of sharp needle and subsequent bleed in injectable anaesthesia. The bleeding post surgery was controlled by ten minutes of pressure patching post surgery in both groups.

The most unpleasant steps of the procedure from verbal feedback of patients in both groups A and B showed that the pressure effect of clamp was often the most unpleasant part of the procedure [39.5%], beside injection [32.2%] and surgery [28.8%]. Keeping the pressure time as short as possible will reduce pain and discomfort in these patients, more so in patients using topical gel anaesthesia for surgery. Modifying the chalazion clamp in such a way that less pressure and pain is suffered by the patient while haemostasis is secured is an area that should be looked into by surgeons and biomedical engineers.

No patient in either group had the surgery discontinued on account of inadequate anaesthesia, which implied that the levels of pain might differ in the two groups but there was sufficient anaesthesia for the patient to tolerate surgery. Systemic complications from anaesthesia was not observed in the study because of the routes of administration and the relatively small dose (1.5 mls of 2% lidocaine) used for this study.

Ideally, the operating surgeon should have been kept ignorant of the group allocation of patients. Ethical consideration precluded the use of normal saline as placebo for injection and methyl cellulose as placebo for gel. However it would have been impossible to compare the pain scores for anesthetic administration which is one of the main outcome measures in this study if the surgeon had used these placebos. These considerations also informed the non-usage of placebos in previous research works^{11,19}. The subjectivity of pain and difficulty of intra operative pain assessments were also limitations in this study. Pain assessment may be masked by ethnic and cultural background of the patients.

Lidocaine gel used in this study is currently not readily available within Nigeria and this may make it relatively costlier to procure by patients. On the other hand, injectable lidocaine is widely available. However, lidocaine gel is associated with less local complications and needle related injury to the patients and surgeons which on the long run makes it a cheaper and safer mode of anaesthesia. More so, no special skill is needed to apply the gel lidocaine as is required with the injectable solution. This also makes it a preferable option in the hand of paramedics (ophthalmic medical assistants and nurses) who perform this minor ocular surgery in places where they have been trained to perform it.

In conclusion, Lidocaine 2% gel is an effective alternative to injectable lidocaine in chalazion surgery. Though the intra operative pain score was more in the gel group, the total pain experienced by patients in the procedure (anaesthesia plus surgery) was lower in the gel group. The gel also had less local complications compared to injectable anaesthesia.

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